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DISTRICT OF NEW JERSEY

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CONNETICS CORPORATION and CONNETICS AUSTRALIA PTY. LTD., Plaintiffs, v. AGIS INDUSTRIES (1983) LTD., Defendant.	Civ. 05-5038 (GEB) **REDACTED PUBLIC VERSION**

DEFENDANT'S BRIEF IN OPPOSITION TO PLAINTIFFS' REQUEST FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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I. INTRODUCTION.

Connetics cannot obtain injunctive relief preventing the immediate launch of Agis' non-infringing generic product because:

- Connetics has no chance of succeeding on the merits of its infringement claim, let alone a reasonable likelihood of success;
- Connetics has not proven (and cannot prove) that it will suffer any irreparable harm absent immediate injunctive relief;
- Agis will suffer severe harm if an injunction issues; and
- the public will suffer considerable harm if Connetics succeeds in continuing to keep Agis' affordable generic drug product off the market.

In other words, Connetics cannot satisfy any, let alone all, of the factors required to obtain a preliminary injunction.

With its motion, Connetics makes the same last-ditch effort to stave off generic competition that other brand companies have made. Indeed, last year in this District alone, at least three brand companies unsuccessfully sought injunctive relief in ANDA cases. *Novartis Corp. v. Teva Pharms. USA*, No. 04-4473, 2007 WL 1695689 (D.N.J. June 11, 2007) (denying injunctive relief) (Ackerman, J.); *Altana Pharma v. Teva Pharms. USA*, -- F. Supp. 2d --, 2007 WL 2688917 (D.N.J. Sept. 6, 2007) (Linares, J.); *Novartis Pharms. v. Teva Pharms. USA*, No. 05-1887, 2007 WL 2669338 (D.N.J. Sept. 6, 2007) ("*Teva*") (Cavanaugh, J.); *see also Collagenex Pharms. v. IVAX Corp.*, 375 F. Supp. 2d 120 (E.D.N.Y. 2005).

The fact is, but for Connetics' baseless suit, Agis would have been able to go to market back in August 2006 – *over eighteen months ago*. Enough is enough. Agis has the right to begin marketing its non-infringing product and the public has the right to begin enjoying the savings that flow from generic competition.

II. BACKGROUND.[1]

In 2005, Agis filed an abbreviated new drug application ("ANDA") with the FDA seeking approval to market a generic version of Connetics' Olux® branded drug product. Olux®, a topical foam used to treat skin disease, contains clobetasol propionate as the active ingredient. Because Agis sought approval to begin marketing prior to expiration of U.S. Patent No. 6,126,920 ("the '920 patent"), its ANDA contains a so-called "paragraph IV" certification, stating that the patent is invalid, unenforceable, or not infringed by Agis' ANDA product. As required by law, Agis sent Connetics notice of its ANDA filing. To delay generic competition, Connetics filed suit in October 2005. FDA tentatively approved Agis' ANDA on August 30, 2006 (Ex. 7) because Connetics' lawsuit prevented the agency from granting immediate final approval at that point.[2] *See* 21 U.S.C. § 355(j)(5)(B)(iii). FDA granted final approval to Agis' ANDA on March 10, 2008, upon expiration of the statutory 30-month stay period. (Ex. 28).

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[1] Agis' supporting summary judgment memorandum contains a more detailed statutory and factual background discussion. (*See* Dkt. #93 at 2-9).

[2] "Ex. __" refers to an exhibit attached to the Declaration of Melissa E. Flax submitted herewith.

This case is not complicated and the relevant facts are few. The Court need only construe the two disputed claim terms and then look at the components and pH of Agis' ANDA product (direct infringement) and any evidence of indirect infringement by Agis. In doing so, the Court will see that Connetics cannot establish any, much less a clear, likelihood of success.

Connetics' brief never sets forth the two independent claims at issue, and for good reason: the actual claim language shows the fatal flaws in Connetics' litigation-driven claim construction. Claim 1 provides:

> 1. *A method* of treating a skin disease susceptible to treatment with corticosteroid active substances, said method comprising administering topically to a patient in need thereof, an effective amount of a foamable *pharmaceutical composition comprising* a corticosteroid active substance, a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent; a propellant; ***and*** *a buffering agent present in an amount sufficient to provide a pH within the range of 3.0 to 6.0.*

(Ex. 1 (emphasis added)). All claims depending from claim 1 also require, *inter alia*, a "buffering agent;" a propellant; and the "buffering agent" must maintain the pH "within the range of 3.0 to 6.0." 35 U.S.C. § 112, ¶ 4. Independent claim 4 provides:

> 4. *A method* of treating a skin disease susceptible to treatment with corticosteroid active substances, said method comprising administering topically to a patient in need thereof an effective amount of a foamable *pharmaceutical composition comprised of* a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent a propellant; an active isomer of an isomeric corticosteroid active substance; ***and***

an amount of a buffering agent effective to stabilize the active isomer against isomerization to a less active isomer.

(Ex. 1 (emphasis added)). Thus, claim 4 requires, *inter alia*, the presence of a "buffering agent;" a propellant; and the "buffering agent" must "stabilize the active isomer against isomerization to a less active isomer."

Given the unambiguous claim language, as well as the specification and prosecution history, Connetics cannot prove infringement at least because:

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- even if Connetics could establish direct infringement, it has no proof of indirect infringement (all claims).

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Its efforts fail. Connetics' motion must be denied because it has no chance of success on the merits, to say nothing of the fact that it cannot establish any irreparable harm.

III. ARGUMENT.

The Federal Circuit considers a preliminary injunction to be a "drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech.*, 995 F.2d 1566, 1568 (Fed Cir. 1993). To obtain such relief, the movant must demonstrate: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

"Although the Court must generally weigh all four of these factors, 'a movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.,* likelihood of success on the merits and irreparable harm.'" *Altana*, 2007 WL 2688917, at *5 (denying injunctive relief in an ANDA case) (quoting *Amazon.com*, 239 F.3d at 1350). Here, Connetics cannot establish any of the factors needed for obtaining the extraordinary relief requested, and certainly cannot establish either irreparable harm or a reasonable likelihood of success on the merits. Its motion must be denied.

A. Connetics' Motion Must Be Denied Because It Has Not Established, And Cannot Establish, Any Irreparable Harm.

This Court can resolve Connetics' motion quickly, without delving into the details of claim construction or infringement, because Connetics has no irreparable

harm and thus the requested injunction must be denied. *Novartis*, 2007 WL 1695689, at *3; *Amazon.com*, 239 F.3d at 1250.

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[5] "Wesolowski Dec." refers to the Declaration of John Wesolowski submitted herewith.

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Because Connetics cannot establish that it will suffer any irreparable harm, its motion must be denied regardless of the Court's analysis of the remaining factors. *Altana*, 2007 WL 2688917, at *5; *Amazon.com*, 239 F.3d at 1350.

B. Connetics' Motion Must Be Denied Because It Cannot Prove A Reasonable Likelihood Of Success On Its Infringement Claim.[7]

Connetics "must make a 'clear' showing of likely success on the merits." *Teva*, 2007 WL 2669338, at *15; *see also Novartis*, 2007 WL 169589, at *25 (denying preliminary injunction where brand company "failed to demonstrate that

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[7] Agis' summary judgment opening and reply briefs contain a more detailed claim construction and non-infringement discussion. (Dkt. #93, #109).

[the ANDA filer's] non-infringement defense lack[ed] substantial merit" and thus "failed to carry its burden of showing that it will likely prove that [the ANDA filer's] formulation infringes"). But Connetics' motion for injunctive relief takes the same approach as its opposition to Agis' summary judgment motion – concoct a claim construction that ignores or contradicts the intrinsic evidence; throw out a bunch of irrelevancies, half-truths, and unsupported factual assertions; construct and knock down straw-men; and argue based on unproven and conclusory statements by its experts. These tactics will not help Connetics survive summary judgment and they certainly do not constitute a "'clear' showing of likely success on the merits."

1. Claim Construction.

Determining the "scope and meaning" of the asserted claims requires the Court to look "to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, two terms require construction: "buffering agent" (all claims) and "to provide a pH within the range of 3.0 to 6.0" (claim 1 and all dependent claims). An objective review of the intrinsic evidence leads to but one conclusion: (1) "buffering agent" means a separate component consisting of a weak acid and its conjugate salt (sometimes called its conjugate base) that is added to the formulation; and

(2) "to provide a pH within the range of 3.0 to 6.0" means the "buffering agent" is present to maintain the pH of the composition within the range of 3.0 to 6.0.

a. "Buffering Agent".

A "buffering agent" is a component of the formulation, separate and apart from the other ingredients. In refusing to set out the actual claim language, Connetics unwittingly concedes a claim construction point. (Pl. Br. 3-4). Specifically, Connetics explains that the compositions in the '920 patent require a "corticosteroid (such as clobetasol propionate), a quick-break foaming agent, a propellant, and a buffering agent." (*Id.* at 3). Connetics also lists the quick-break foaming agent's ingredients: "an 'aliphatic' alcohol (such as ethanol), water, a 'fatty' alcohol (such as cetyl or stearyl alcohol), and a 'surface active agent' (such as polysorbate)." (*Id.* at 3-4). Consequently, Connetics concedes that a "buffering agent" is a specifically-added component of the formulation, separate and apart from the other enumerated ingredients (*i.e.*, from the active drug substance; the ingredients of the quick-break foaming agent, along with any impurities in those ingredients; and the propellant). A look at the claims confirms this to be true:

- claim 1 requires, *inter alia*, "a foamable pharmaceutical composition comprising a corticosteroid active substance, a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent; a propellant; *and a buffering agent*"; and

- claim 4 requires a "foamable pharmaceutical composition comprised of a quick-break foaming agent that comprises an aliphatic alcohol, water, a fatty alcohol and a surface active agent a propellant; an

> active isomer of an isomeric corticosteroid active substance; *and an amount of a buffering agent . . . .*"

(Ex. 1 (emphasis added); *see also* Ex. 3 ¶ 36; Ex. 6 at 30-32, 37). Unasserted claims 13 and 15 underscore that the "buffering agent" is an independent component, separate and apart from the other listed ingredients, by identifying the precise "buffering agent" to be added to the composition. (Ex. 1).

The prosecution history further confirms that a "buffering agent" is a separate component added to the composition. Specifically, the inventors made several arguments to the PTO contrasting the alleged invention of the '920 patent with the prior art. The inventors, for instance, repeatedly emphasized that the '920 patent compositions must contain a "buffering agent" and unambiguously disclaimed prior art compositions that they stated lacked a "buffering agent."

The PTO rejected the claims of the '920 method patent as obvious over European Patent Application 0 484 530 A1 ("EPA") and PCT application WO 85/01876 ("WO"). (Ex. 9 at AGIS 2272-73). EPA discloses compositions containing inactive ingredients such as aliphatic alcohol, water, fatty alcohol, surface active agents, propellants, and a glycol (such as propylene glycol). (Ex. 10 at AGIS 18800-03, 18825, 18816; Ex. 3 ¶ 42; Ex. 6 at 66-69, 78-79). WO discloses foam compositions containing such inactive ingredients as aliphatic alcohol, water, fatty alcohol, surface active agents, emollients (such as propylene glycol), propellants, and, optionally, organic acid salts. (Ex. 11 at AGIS 18833-37;

Ex. 3 ¶ 41; Ex. 6 at 69-72). In response, the inventors emphasized that their alleged invention, unlike the EPA and WO compositions, requires the addition of a "buffering agent":

> [I]t is one aspect of the present invention to overcome the problems of instability of corticosteroids in liquid compositions. The present inventors have discovered that the stability of such preparations may be improved by controlling the acidity of the composition and *the claims thus require the presence of a buffering agent* to maintain the pH of the composition within the range of 3 to 6. . . . . EPA provides no teaching or suggestion that the stability of corticosteroids in liquid compositions may be improved by controlling the acidity of the composition and *there is clearly no teaching that would motivate the person of skill to include a buffering agent* to *maintain* the pH of the composition within the range of 3 to 6. *This teaching is only provided by Applicants' disclosure.*
>
> * * *
>
> Moreover, while the compositions of EPA and WO may or may not be analogous, even if as asserted by the Examiner, one were motivated to replace the biocidal agent of WO with the steroid of EPA, the claimed invention would not be achieved. *Applicants' compositions require the presence of a buffering agent to maintain the pH within the range of 3 to 6.* This is a requirement neither taught nor even recognized by either of EPA or WO.

(Ex. 9 at AGIS 2276-78 (emphasis added)). These passages also demonstrate the inventors' emphasis on the requirement that the buffering agent "maintain" the composition's pH within the specific range of 3.0 to 6.0.

The fact is, the inventors had no choice but to distinguish their alleged invention from the prior art based upon the criticality of adding a "buffering agent" as a separate component – the prior art compositions contained all of the inactive ingredients of the '920 patent compositions except a "buffering agent":

'920 Patent	WO	EPA	EP 331,489 A2	Woodford et al.
corticosteroid		X		X
aliphatic alcohol	X	X	X	X
water	X	X	X	X
fatty alcohol	X	X	X	X
surface active agent	X	X	X	X
propellant	X	X	X	X
buffering agent				

(Exs. 10-13; Ex. 3 ¶¶ 41, 42, 47).[8]

A "buffering agent" is a weak acid and its conjugate salt. Having established that a "buffering agent" is a component separate and apart from the other ingredients (including any impurities in those ingredients), the question now is: What is a "buffering agent?" The claims answer this question, too: a "buffering agent" is a weak acid and its conjugate salt, which is consistent with how a person of skill in the art understands that term. (Ex. 3 ¶¶ 22-23; Exs. 21-25 (relevant literature references identifying a "buffering agent" as a weak acid/conjugate salt)). Claims 13 and 15, for example, specify the "buffering agent" to be added to the composition as a weak acid/conjugate salt "selected from the group consisting of a citrate buffer, an acetic acid/sodium acetate buffer and a phosphoric acid/sodium phosphate buffer" or as the weak acid/conjugate salt "Citric Acid Anhydrous BP [and] Potassium Citrate." (Ex. 1).

[8] The prior art EP 331,489 A2 and Woodford et al. references were not before the PTO, but can be considered during claim construction. *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999).

The specification confirms the ordinary meaning of "buffering agent" by:

- emphasizing that adding a separate "buffering agent" to the formulation is critical to the claimed invention (*see, e.g.*, Ex. 1, col. 3, ll. 32-45);

- showing what the inventors meant by the term "buffering agent," *i.e.*, that a "buffering agent" is a component of the pharmaceutical formulation consisting of a weak acid and its conjugate salt (sometimes called its conjugate base) (*id.*);

- describing both suitable and preferred "buffering agents," all of which are combinations of a weak acid and its conjugate salt (*id.*); and

- providing an example of a pharmaceutical composition, which contains citric acid anhydrous BP/potassium citrate as the "buffering agent" (a weak acid and its conjugate salt) (*id.* col. 5, ll. 1-15).

And, of course, all of the "buffering agents" in the '920 specification are comprised of a weak acid and its conjugate salt. (Ex. 3 ¶ 35; Ex. 6 at 28-30).

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Not true.

The specification certainly gives examples of "buffering agents" that can be used in the alleged invention and every example is a specific weak acid/conjugate salt combination. But as Connetics well knows, Agis has *never* argued that "buffering agent" is limited to the specific weak acid/conjugate salt pairs listed in the patent or the preferred embodiments. Indeed, there are weak acid/conjugate salt combinations other than those in the patent, including, for instance, lactic

acid/sodium lactate. Agis merely used the specification to help determine what the term "buffering agent" means. Agis does so because the Federal Circuit mandates that "[c]laims must be read in view of the specification, of which they are a part." *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001); *Phonometrics v. N. Telecom*, 133 F.3d 1459, 1466 (Fed. Cir. 1998).

Indeed, the Federal Circuit construed the claim term "solubilizer" in a pharmaceutical patent to mean "surfactants" based upon statements in the specification that described "the solubilizers suitable" for the invention as surfactants; the fact that every one of the preferred "solubilizers" listed in the specification was a surfactant; and the fact that in each of the examples in the specification, the preferred "solubilizer" was a surfactant. *Astrazeneca AB v. Mutual Pharm.*, 384 F.3d 1333, 1339-41 (Fed. Cir. 2004). Here, as in *Astrazeneca*, the '920 patent inventors made clear, through the statements and examples in their specification, that they meant the term "buffering agent" to be the combination of a weak acid and its conjugate salt. Agis has violated no claim construction rules.

Connetics' construction necessarily fails. To avoid defeat, Connetics must, and does, ask this Court to construe "buffering agent" differently than defined in the intrinsic evidence and used in the relevant literature. Rather than proffering an actual definition of the term,

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Connetics cannot "demonstrate that [Agis'] non-infringement defense lacks substantial merit" with this approach. *Novartis*, 2007 WL 169589 at *25.

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For one, Connetics' construction is inconsistent with the intrinsic evidence defining a "buffering agent" and thus must fail because the law prevents Connetics from offering a construction in litigation that "alter[s] the indisputable public record consisting of the claims, the specification and the prosecution history." *Southwall Techs. v. Cardinal IG*, 54 F.3d 1570, 1578 (Fed. Cir. 1995).

Further, as previously discussed, the existence of a "buffering agent," separate and apart from the other inactive ingredients, is the critical difference the

inventors repeatedly said existed between the claimed invention and the prior art. Construing "buffering agent" as Connetics suggests would impermissibly eliminate the sole difference between the '920 patent compositions and the prior art. But Connetics cannot avoid the content of the prior art or the inventors' unequivocal representations. *Gillespie v. Dywidag Sys. Int'l*, 501 F.3d 1285, 1291 (Fed. Cir. 2007) ("[t]he patentee is held to what he declares during the prosecution of his patent"; holding that claim construction could not encompass features in prior art that were distinguished in PTO arguments); *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) ("A patentee may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement.").

Moreover, the Federal Circuit mandates that claims must be construed to avoid rendering limitations superfluous. *See Merck & Co. v. Teva Pharms. USA*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (refusing to adopt construction that rendered a term "excess verbiage").

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Finally, calling it "similar" to this case, Connetics cites *Roche Diagnostics Corp. v. Inverness Med. Tech.*, 186 F. Supp. 2d 914 (S.D. Ind. 2002), in arguing for a "functional" construction of "buffering agent." (Pl. Br. 14 n.6). This case is irrelevant. The patent there claimed a buffer-containing *medical device* used to test blood. *See* 186 F. Supp. 2d. at 924-25. The *Roche* court simply construed the term "buffer" as used in the art relevant to the patent-in-suit – an art decidedly different than the one at issue for the '920 method patent. *See id.*

b. "To provide a pH within the range of 3.0 to 6.0".

Claim 1 (and all dependent claims) requires a pharmaceutical composition containing "a buffering agent present in an amount to provide a pH within the range of 3.0 to 6.0." The inventors did not use broadening words, such as "approximately" or "about," nor did they quantify an amount above or below this precise range. "Without broadening words that ordinarily receive some leeway," the law holds the inventors to the precise range recited. *Jeneric/Pentron v. Dillon Co.*, 205 F.3d 1377, 1381 (Fed. Cir. 2000).

Consistent with the claims, the specification refers to the pH range of the claimed composition only in precise terms: "it is desirable generally to buffer the composition to pH 3.0-6.0, preferably 4.0-5.0." (Ex. 1, col. 3, ll. 39-41). The inventors thus contemplated that the pH of any claimed composition would be maintained within the precise range of 3.0-6.0. This is further confirmed by the

fact that the preferred pH range falls squarely within 3.0-6.0, as well as the fact that the specification does not mention a pH above 6.0 or below 3.0.

Finally, as set forth above, the inventors repeatedly told the PTO that the compositions of the '920 patent "require the presence of a buffering agent to maintain the pH within the range of 3 to 6." (Ex. 9 at AGIS 2278; *see also* AGIS 2276-77)). In doing so, the inventors made plain both that the pH of the composition must *fall within* the range of 3.0 to 6.0 and be *maintained* within that range by the "buffering agent." From these repeated representations, the inventors did not intend to (and did not) claim a formulation, for example, with a pH of 5.8 one month and 6.8 the next because it does not maintain a pH between 3.0 to 6.0. Again, "[t]he patentee is held to what he declares during the prosecution of his patent." *Gillespie*, 501 F.3d at 1285.

Connetics never offers its own construction of this term and thus the Court should adopt Agis', which is consistent with all of the intrinsic evidence.

c. Connetics' Improper Reliance On Extrinsic Evidence.

Where a review of the intrinsic evidence "resolve[s] any ambiguity in a disputed claim term . . . it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583. And in no circumstance may extrinsic evidence be used "to arrive at a claim construction that is at odds with the intrinsic evidence." *Playtex Prods. v. Procter & Gamble Co.*, 400 F.3d 901, 908 & n.1 (Fed. Cir. 2005).

Connetics' extrinsic evidence cannot be considered. First, resort to any extrinsic evidence is improper because the intrinsic evidence here unambiguously defines the relevant claim terms. Second, resort to Connetics' extrinsic evidence in particular is improper because its experts try to adopt a definition of "buffering agent" that contradicts the intrinsic evidence – both how the inventors use the term in the patent and prosecution history, and with published literature in the relevant art. Thus, if this Court were to look at extrinsic evidence, only Agis' experts' opinions can be considered because they are consistent with the intrinsic evidence and relevant published literature. (*See* Exs. 14-16, 21-25; *see also* Ex. 17).[9]

2. No Direct Infringement – Literal Infringement.

The '920 patent is a method patent. (Ex. 1). Agis does not and will not administer its proposed ANDA product to patients. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 & n.7 (Fed. Cir. 2003). Connetics thus must prove that Agis is indirectly infringing, which requires direct infringement by others. *Joy Techs. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993). "Literal infringement requires that the accused device embody every element of the claim." *Builders Concrete v. Bremerton Concrete Prods.*, 757 F.2d 255, 257 (Fed. Cir. 1985).

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Statements in applications unrelated to the '920 patent are irrelevant when construing the terms of that patent. *Texas Digital Sys. v. Telegenix*, 308 F.3d 1193, 1211 (Fed. Cir. 2002); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1104 (Fed. Cir. 2002).

Connetics has no chance of success because Agis' ANDA product does not contain every element of the asserted claims. At the very least, Agis shows that Connetics "has failed to demonstrate that [Agis'] non-infringement defense lacks substantial merit," which means Connetics' motion must be denied. *Novartis*, 2007 WL 1695689, at *25; *Collagenex*, 375 F. Supp. 2d at 137-38 (same).

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Further, Connetics cannot prove infringement even under its improper construction.

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3. No Direct Infringement – Doctrine Of Equivalents.

a. Prosecution History Estoppel Applies Here.

Prosecution history estoppel "limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent." *Southwall*, 54 F.3d at 1579. A patentee's arguments to the PTO create an estoppel, regardless of whether those arguments were necessary to distinguish the patentee's invention over the prior art or for the allowance of a claim. *Laitram Corp. v. Morehouse Indus.*, 143 F.3d 1456, 1464 (Fed. Cir. 1998).

Connetics is estopped from asserting infringement under the doctrine of equivalents because the patentees repeatedly told the PTO that the '920 patent does not encompass REDACTED

Again, the PTO rejected the claims as being unpatentable over prior art references EPA and WO. (Ex. 9 at AGIS 2272-73). In response, the patentees repeatedly and unmistakably said that the compositions of the '920 patent "*require the presence of a buffering agent* to maintain the pH within the range of 3 to 6" and that "[t]his is a requirement neither taught nor even recognized by either of EPA or WO." (*Id.* at

AGIS 2276; AGIS 2278). The patentees also told the PTO that if one were to "replace the [the active ingredient] of WO with the steroid of EPA, the claimed invention would not be achieved." (*Id.* at AGIS 2278).

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b. A Finding Of Infringement Under The Doctrine Of Equivalents Would Violate The "All Elements Rule."

Even if Connetics could assert infringement under the doctrine of equivalents, any infringement finding would violate the "all limitations rule," which holds that "an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent." *Freedman Seating v. Am. Seating*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). This rule "requires

that equivalence be assessed on a limitation-by-limitation basis, as opposed to from the perspective of the invention as a whole." *Id.* In fact, "an element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation." *Id.*

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c. Connetics' Equivalence Argument Must Fail.

Even if Connetics could cobble together a doctrine of equivalents argument for every other claim limitation, Connetics cannot win REDACTED Connetics' stab at an equivalents argument suffers from the same fatal flaws as its literal infringement argument.

REDACTED Connetics also ignores the fact that the '920 patent is a *method* patent, not a composition patent.

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4. Connetics Has No Evidence Of Indirect Infringement.

To prevail on contributory infringement, Connetics must prove, *inter alia*, that Agis' ANDA composition has no substantial non-infringing uses and that Agis *knew* its composition was especially made or "adapted for use in an infringement of [the '920] patent." 35 U.S.C. § 271(c); *Aro Mfg. Co. v. Convertible Top Replacement*, 377 U.S. 476, 488 (1964) (§ 271(c) requires a showing that the alleged contributory infringer "knew that the combination for which his component was especially designed was both patented and infringing"); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004) (same); *BMC Res. v. Paymentech, L.P.*, 498 F.3d 1373, 1381 (Fed. Cir. 2007) (same).

With respect to inducement, "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). This requires Connetics to prove that Agis knowingly induced another to commit an infringing act, *i.e.*, Agis actively and knowingly aids and abets another's direct infringement. The Federal Circuit has held that "the intent requirement for inducement requires more than just intent to cause the acts that produce direct infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). Rather, Connetics must prove that Agis has an affirmative intent to cause direct infringement. *See id.*; *MEMC Elec. Mats. v. Mitsubishi Mats. Silicon Corp.*, 420 F.3d 1369, 1378 (Fed.

Cir. 2005); *Metro-Goldwyn-Mayer Studios v. Grokster, Ltd.*, 545 U.S. 913, 936-37 (2005); *Manville Sales v. Paramount Sys.*, 917 F.2d 544, 553 (Fed. Cir. 1990).

The only support Connetics offers for its indirect infringement claim is the

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. But the law requires Connetics to prove more than that Agis intended to cause the acts that could produce direct infringement; it "requires a mens rea." *BMC*, 498 F.3d at 1373, 1381; *DSU*, 471 F.3d at 1306; *Aro Mfg.*, 377 U.S. at 488; *Golden Blount*, 365 F.3d at 1061.

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Thus, Connetics lacks any evidence regarding the specific intent needed to sustain a claim for indirect infringement. Consequently, even if Connetics had a likelihood of success on direct infringement (it does not), it has no chance of success vis-à-vis indirect infringement.

C. The Balance Of The Harms Tips Decidedly In Agis' Favor.

Agis will suffer considerable harm if an injunction issues.

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D. The Public's Interest Favors Denial Of Connetics' Motion.

"[T]he public interest [favors] receiving generic competition to brand-name drugs as soon as is possible." *Boehringer Ingelheim v. Shalala*, 993 F. Supp. 1, 2-3 (D.D.C. 1997). Indeed, Congress enacted Hatch-Waxman Act "to get generic drugs into the hands of patients at reasonable prices–fast." *In re Barr Labs.*, 930

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F.2d 72, 76 (D.C. Cir. 1991). This, in and of itself, favors denial. Furthermore, in cases such as these, when an injunction is improperly granted, the adverse effects on the public interest are irreparable. If Connetics obtains an injunction but Agis later prevails, there is no way to compensate consumers for the millions of dollars paid to purchase Olux® at monopolistic prices while the injunction was in place. *Teva*, 2007 WL 2669338, at *15. Denying Connetics' motion, however, will permit immediate, substantial savings to patients. The public interest thus favors denial. *Collagenex*, 375 F. Supp. 2d at 140-41.

E. Connetics Must Post A Sufficient Bond.

In the event the Court decides to grant Connetics' injunction, Connetics must post a bond to compensate Agis for damages if Agis prevails on the merits. *See* Fed. R. Civ. P. 65(c). And because Agis risks significant monetary damages if an injunction is wrongfully entered, the bond requirement of Rule 65(c) is mandatory. *See Hoxworth v. Blinder, Robinson & Co.*, 903 F.2d 186, 210 (3d Cir. 1990) (failure to require the posting of a bond constitutes "reversible error").

In using its discretion in setting the bond amount, this Court "should err on the high side" because damages for an erroneous preliminary injunction may not exceed the amount of the bond. *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000); *see also* 13 James Wm. Moore et al., MOORE'S FEDERAL PRACTICE § 65.50[1] (3d ed. 2003). Here, the bond that Connetics posts should be

at least equal to the amount that Agis can reasonably expect for the "payment of such costs and damages as may be incurred or suffered" as a result of being wrongfully enjoined from selling its clobetasol propionate foam products. FED. R. CIV. P. 65(c); *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 349 (S.D.N.Y. 2006).

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IV. CONCLUSION.

For the reasons set forth above, Connetics' motion for preliminary injunctive relief must be denied.

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